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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,079	03/30/2004	Kalpana Kamath	01194-447001 / 02-160	5482
26161	7590	12/17/2008	EXAMINER	
FISH & RICHARDSON PC			PARVINI, PEGAH	
P.O. BOX 1022				
MINNEAPOLIS, MN 55440-1022			ART UNIT	PAPER NUMBER
			1793	
			NOTIFICATION DATE	DELIVERY MODE
			12/17/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/814,079	<b>Applicant(s)</b> KAMATH ET AL.	
	<b>Examiner</b> PEGAH PARVINI	<b>Art Unit</b> 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 14-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/22/2006, 3/27/2006, 12/1/2005, 10/4/2005,</u>               | 6) <input type="checkbox"/> Other: _____                          |
| <u>8/24/2005, 10/13/2005</u>   |   |



## **DETAILED ACTION**

### ***Election/Restrictions***

Applicants' election of Group I, claims 1-13 in the reply filed on September 5, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claim 1** is rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,468,493 to Chevallier et al.

Chevallier et al. teach porous silica particles or powders which are substantially spherical and preferably have an average size of at least 100 microns (Abstract; column 4, lines 32-37; column 9, line 45; column 10, lines 52-55).

### ***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 2-3** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chevallier et al.

As noted above, Chevallier et al. disclose porous silica particles or powders which are substantially spherical and preferably have an average size of at least 100 microns, for example, 220 microns or 215 microns (Abstract; column 4, lines 32-37; column 9, line 45; column 10, lines 52-55). The disclosure of “at least 100 microns” is taken to have overlapping ranges with the recitation in claim 2 which recites “at most about 1500 microns”. It is noted that overlapping ranges have been held to establish *prima facie* obviousness. MPEP § 2144.05.

Chevallier et al. disclose pore volume of between 175 and 275A° (i.e. about 17.5 to 27.5 nm). The reference, further, disclose pore diameter of less than or equal to 400A° (i.e. about 40 nm). It is to be noted that there is overlapping ranges of pore volume in the disclosed range with the one instantly claimed, and overlapping ranges have been held to establish *prima facie* obviousness. MPEP § 2144.05.

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**Claims 4-13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Chevallier et al. in further view of US Patent Application Publication No. 2003/0206864 to Mangin.

Regarding claims 4-9 and 12-13, Chevallier et al. teach porous silica particles or powders which are substantially spherical and preferably have an average size of at least 100 microns, for example, 220 microns or 215 microns as detailed above.

Furthermore, Chevallier et al. disclose that the pore volume of the pores with a diameter of between 100 to 300 Å (i.e. about 10 to 300 nm) is at least 0.82 cm<sup>3</sup>/g; the reference, in an embodiment discloses that, for example, the pore volume represented by the pores of less than 400 Å (i.e. about 40 nm) is about 1.03 cm<sup>3</sup>/g (column 7, lines 35-38; column 9, lines 30-45; column 10, lines 40-53; column 11, lines 45-60).

Chevallier et al. do not expressly disclose the suspension of said silica particles in a carrier fluid.

Mangin, drawn to embolic particle dispersions, contrast agents and compositions suitable for affecting embolization or occlusion of a vessel or a duct which particles, agents and compositions are visible under ultrasound, teach the use of a compatible carrier fluid in said composition with the embolic particles and agents (Abstract; [0017]) wherein the compatible carrier fluid may be saline ([0063]). Mangin et al., additionally, disclose the use of silica particles as the embolic particles ([0015], [0026]) wherein the embolic particles comprise one or more voids ([0015]). Thus, although the reference may not literally disclose porous embolic particles, based on the disclosure above, it

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would have been obvious to have porous silica particles as the reference discloses silica particles as embolic particles having voids therein. Furthermore, the reference makes it obvious that the choice of particle size is on the basis of the size of the vessel to be occluded, the desired duration of occlusion, the type of abnormality to be treated, and is substantially commensurate with the desired microbubble size of the gas which fills the voids to make the embolic particles visible by ultrasound ([0003], [0047]).

Additionally, Mangin teaches that the embolic particles may be used in a combination with drugs or toxins or with chemotherapeutic agents to increase the therapeutic value of the composition ([0067]). Moreover, Mangin teaches that the embolic particles are immersed in a sterile physiological solution ([0063]). Finally, Mangin et al. disclose that the embolic particles may be of a wide variety of shapes such as spherical which is the most preferred shape ([0029]).

It would have been obvious to one of ordinary skill in the art to utilize the porous silica particles of Chevallier et al. in a composition comprising a contrast agent and a carrier fluid such as saline as that taught by Mangin motivated by the fact that it is known to use silica particles in compositions for affecting embolization as Mangin teaches that silica particles, with preferably spherical shape, with more than one voids therein are known in the art to be used in such compositions (Mangin, [0026]) wherein the size of said particles depends on a number of factors such as the size of the vessel to be occluded, the desired duration of occlusion, and the type of abnormality to be treated. Therefore, the use of porous silica particles in spherical shape is known in the art to be used in carrier fluids to be injected in the body with a contrast agent. The use

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of contrast agent, as known in the art and disclosed by Mangin, make is available to obtain ultrasound images of tissues and organs.

Regarding claims 10 and 11, it is to be noted that while the combination of references discloses porous silica particles in spherical shapes which have a particle diameter of a range that has overlapping ranges with the one instantly claimed and wherein said silica is dispersed in saline, the properties of loss of attrition resistance of about 0.1% by weight or less and a tolerance of about 10 nm or less on the mean pore diameter for 70% or more of the pore volume in the pore volume distribution are expected to follow from the composition of the references as combined absence clear evidence showing the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PEGAH PARVINI whose telephone number is (571)272-2639. The examiner can normally be reached on Monday to Friday 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/P. P./  
Examiner, Art Unit 1793

/J.A. LORENZO/  
Supervisory Patent Examiner, Art  
Unit 1793